

The Health Equity and Middle Eastern and North African Community Inclusion Act of 2023 would add a Middle Eastern and North African category to the definition of “racial and ethnic minorities” used by the Office of Minority Health. Additionally, it would direct the Department of Health and Human Services to use this data to conduct a comprehensive study of the unique patterns and health outcomes in MENA populations.

I want to thank Representative TLAIB for joining me in introducing this bill. I look forward to working with my colleagues to take this important step to reduce health disparities.

By Mr. DURBIN:

S. 2907. A bill to improve medical device recall notifications by amending the Federal Food, Drug, and Cosmetic Act to establish an electronic format for device recall notifications, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mr. DURBIN. Madam President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 2907

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medical Device Recall Improvement Act”.

SEC. 2. REGULATION OF MEDICAL DEVICE RECALLS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), is amended by inserting after section 518A of such Act the following:

“SEC. 518B. ELECTRONIC NOTIFICATION FORMAT FOR DEVICE RECALLS.

“(a) ELECTRONIC NOTIFICATION FORMAT FOR DEVICE RECALLS.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Medical Device Recall Improvement Act, the Secretary shall publish a form and manner for notifications of a recall.

“(2) CONTENT.—The form and manner prescribed by the Secretary under paragraph (1) shall—

“(A) be electronic;

“(B) include mandatory data elements, including—

“(i) the name of the manufacturer or importer;

“(ii) the contact information and address of the manufacturer or importer;

“(iii) the specific reason for the correction or removal from the market of the device;

“(iv) the specific device of the manufacturer or importer subject to such recall;

“(v) the unique device identifier of the device, including, as applicable, the device identifier and any production identifier;

“(vi) information for device user facilities and health professionals with regard to the device and such recall; and

“(vii) information for patients with regard to the device and such recall, including—

“(I) the risk presented by the device; and

“(II) any action that may be taken by, or on behalf of, such patients to eliminate or reduce such risk; and

“(C) include optional data elements as the Secretary determines to be appropriate.

“(b) NOTIFICATIONS.—

“(1) NOTIFICATIONS TO THE SECRETARY.—

“(A) IN GENERAL.—Beginning 180 days after the Secretary establishes the form and manner for recall notifications under subsection (a), a manufacturer or importer of a device shall submit notifications required under section 519(g) to the Secretary through the electronic notification format established under subsection (a).

“(B) REVIEW REQUIREMENT.—

“(i) INITIAL REVIEW.—Not later than 2 business days after receipt of a notification described in subparagraph (A), the Secretary shall conduct an initial review of such notification.

“(ii) RESPONSE OF THE SECRETARY.—Not later than 3 business days after the completion of such review, the Secretary shall inform the manufacturer or importer of the information the Secretary determines, through the initial review under clause (i), should be shared with device user facilities and health professionals.

“(2) NOTIFICATIONS TO DEVICE USER FACILITIES AND HEALTH PROFESSIONALS.—

“(A) INITIAL NOTIFICATIONS.—A manufacturer or importer shall submit notifications to device user facilities and health professionals through the electronic notification format established under subsection (a) after an initial review by the Secretary is completed under paragraph (1)(B)(i).

“(B) SUBSEQUENT NOTIFICATIONS.—A manufacturer or importer shall provide notifications in addition to those described in subparagraph (A), as necessary, to device user facilities or health professionals through the electronic notification format established under subsection (a).

“(c) ELECTRONIC DATABASE.—The Secretary shall maintain an electronic database that is publicly accessible, downloadable, and populated with information regarding device notifications made under this section.

“(d) DEFINITIONS.—In this section and in section 518C—

“(1) the term ‘device user facility’ has the meaning given such term in section 519(b)(6); and

“(2) the term ‘recall’ has the meaning given such term in section 518A.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For purposes of conducting activities under this section and hiring personnel to conduct such activities, there is authorized to be appropriated \$6,700,000 for fiscal year 2024, \$1,700,000 for fiscal year 2025, and \$1,000,000 for each of fiscal years 2026 through 2028, to remain available until expended, without fiscal year limitation.

“SEC. 518C. PATIENT NOTIFICATION.

“(a) IN GENERAL.—The Secretary shall require that any recall strategy under section 519(g) provides for notice to patients whom device user facilities and health professionals treated with the device.

“(b) COMPLIANCE.—In accordance with subsection (a), the Secretary shall require recall notifications sent from the manufacturer or importer of the device to—

“(1) include information for device user facilities and health professionals about the risks presented by the device to patients whom device user facilities and health professionals treated with the device; and

“(2) instruct such device user facilities and health professionals to share information under paragraph (1) with patients whom device user facilities and health professionals treated with the device.

“(c) AFFECTED DEVICES.—Subsection (a) shall apply with respect to any class I or class II recall for a class II or class III device that is used outside of device user facilities and—

“(1) implanted in the human body;

“(2) life-sustaining;

“(3) life-supporting; or

“(4) used significantly in pediatric populations.

“(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require device user facilities or health professionals to provide patient information to the manufacturer or importer of the device.”.

SEC. 3. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following

“(jjj) The refusal or failure to submit notifications in accordance with paragraphs (1) and (2) of section 518B(b).

“(kkk) The refusal or failure to provide notice in accordance with section 518C.”.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 355—RECOGNIZING THE CRITICAL IMPORTANCE OF ACCESS TO RELIABLE, CLEAN DRINKING WATER FOR NATIVE AMERICANS AND AFFIRMING THE RESPONSIBILITY OF THE FEDERAL GOVERNMENT TO ENSURE SUCH WATER ACCESS

Mr. BENNET (for himself, Mr. PADILLA, Mr. SCHATZ, Mr. WYDEN, Ms. WARREN, Mr. MERKLEY, Ms. DUCKWORTH, Mr. HICKENLOOPER, Mrs. MURRAY, Mr. BOOKER, Mr. TESTER, Mr. KELLY, Mr. LUJÁN, Mr. KING, Mr. HEINRICH, and Ms. CANTWELL) submitted the following resolution; which was referred to the Committee on Indian Affairs:

S. RES. 355

Whereas access to reliable, clean drinking water is an essential human need that is critical to the public health, well-being, educational attainment, and economic development of all communities in the United States;

Whereas many countries, along with the United Nations, have recognized the urgency of water access by passing laws or resolutions relating to the human right to water, including recognition of this right among indigenous peoples and establishing aggressive targets for achieving universal access to this basic right;

Whereas, in the United States, access to reliable, clean drinking water has long been a significant problem in many Native communities, such that nearly ½ of all Native households in the continental United States still do not have access to reliable water sources or clean drinking water, and Native households are significantly more likely than White households to lack indoor plumbing;

Whereas reliable, clean drinking water may be unavailable to Native households for many reasons, including because—

(1) there is no piped water system connecting to the house;

(2) the water available to the household does not meet minimum protective standards;

(3) the water infrastructure is deteriorating or insufficient; or

(4) Indian Tribes, Alaska Native Villages, and Native Hawaiian communities are unable to support the operation and maintenance needs of existing water infrastructure;

Whereas many Native communities have significant unresolved claims for federally reserved water rights, many of which have

been unresolved for decades and which may not be resolved for many years to come, due in part to the complex and significant issues typically involved in water rights adjudication and settlements;

Whereas the development of water infrastructure on Federal Indian reservations, in particular, has frequently been conditioned on the settlement of Tribal reserved water rights and has been prevented or delayed by—

(1) continuing uncertainty over the status of Tribal water rights;

(2) the years-long process of Tribal water rights settlements; or

(3) conflict over the quantification of Tribal reserved water rights in State water rights adjudications;

Whereas the quantity of water that would be required to supply reliable, clean drinking water to provide for the basic needs of each Native community is typically only a small fraction of the total quantity water allocated to the Native community;

Whereas the trust responsibility of the Federal Government to Indian Tribes, Alaska Native Villages, and Native Hawaiian communities requires the Federal Government to ensure the survival and welfare of Native Americans, and the failure to provide basic water service cannot be reconciled with this trust responsibility;

Whereas the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.) affirmed the trust responsibility of the Federal Government to support Tribal self-governance and self-determination, and these goals cannot be fully realized without addressing inequities, including ensuring access to reliable, clean drinking water for every Tribal community;

Whereas the COVID-19 pandemic provided a stark reminder that access to reliable, clean drinking water to support basic hygiene is a matter of life or death for all individuals of the United States and Native communities suffer disproportionate impacts during epidemics and disasters due to a multitude of factors, including—

(1) persistent economic disadvantages on Federal Indian reservations, in Alaska Native Villages, and in Native Hawaiian communities;

(2) lack of on-reservation affordable and safe housing; and

(3) lack of public health infrastructure, including access to running water;

Whereas, on January 27, 2021, President Biden issued Executive Order 14008 (86 Fed. Reg. 7619; relating to tackling the climate crisis), which provides that it is the policy of the Biden Administration to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and underinvestment in housing, transportation, water and wastewater infrastructure, and health care;

Whereas, through the bipartisan Infrastructure Investment and Jobs Act (Public Law 117-58; 135 Stat. 429) (referred to in this preamble as “IIJA”) and the Inflation Reduction Act of 2022 (Public Law 117-169; 136 Stat. 1818) (referred to in this preamble as “IRA”), Congress has provided funding for the Indian Health Service, the Environmental Protection Agency, and the Bureau of Reclamation to support the construction and repair of Tribal clean water infrastructure, but inadequate resources are available to Tribes to assist them with accessing these construction and repair funding programs, and to support Tribal operation and maintenance of water infrastructure, which is necessary to successfully implement the historic investment in clean water infrastructure;

Whereas many Native communities need technical assistance to ensure that the Native communities can—

(1) access and take advantage of the new construction funding made available through the IIJA and IRA;

(2) develop the managerial, financial, and regulatory framework necessary for a fully functional and self-sustaining utility; and

(3) engage appropriate outside support to assist, as needed;

Whereas advances in water technology, including treatment, sensors, and innovative pipeline materials, can assist in—

(1) accelerating efforts to provide universal access to reliable, clean, and drinkable water for all Native communities; and

(2) enhancing resilience in the face of climate change;

Whereas it is in the interest of the United States, and it is the policy of the United States, that all existing Native communities be provided with safe and adequate water supply systems as soon as practicable; and

Whereas appropriate funding at the level of unmet need and a “whole-of-government” approach among all Federal agencies are both essential to provide a meaningful solution to the lack of access to clean water in Native communities: Now, therefore, be it

Resolved, That—

(1) it is the sense of the Senate that—

(A) access to reliable, clean drinking water is an essential human need, and such access on Federal Indian reservations, Alaska Native villages, and in Native Hawaiian communities is—

(i) critical to the health, well-being, and economic development of the individuals living on those lands and in those communities; and

(ii) integral to maintaining the public health of the people of the United States;

(B) settlement or adjudication of Tribal claims of reserved water rights is not and should not be a prerequisite to the provision of this basic human service to households located in Native communities, nor should the provision of basic human services be used to leverage the resolution of Tribal reserved water rights and claims;

(C) the provision of reliable, clean drinking water to support the domestic requirements of Indian Tribes, Alaska Native Villages, and Native Hawaiian communities is an essential component of the Federal trust responsibility to Native Americans and critical to supporting permanent homelands;

(D) while funding for safe drinking water systems for Native communities received a significant and groundbreaking boost from the Infrastructure Investment and Jobs Act (Public Law 117-58; 135 Stat. 429) (referred to in this resolution as “IIJA”) and the Inflation Reduction Act of 2022 (Public Law 117-169; 136 Stat. 1818) (referred to in this resolution as “IRA”), the funding made available for construction and repair of domestic water systems in Native communities is not a complete solution;

(E) technical assistance is urgently needed to allow Native communities to plan and design the systems necessary to remedy the longstanding problem of lack of access to clean drinking water and bring those plans to the “shovel ready” stage where Native communities can take advantage of available construction funding;

(F) Native communities need support to develop the managerial, financial, and regulatory capacity necessary for a fully functional and self-sustaining utility and to support the operation and maintenance of water systems; and

(G) further measures are necessary to ensure that the benefits of the historic investments made by the IIJA and IRA in infrastructure are fully realized; and

(2) the Senate—

(A) calls upon the Federal executive branch to—

(i) work in collaboration with the relevant Native governmental entities and State and local jurisdictions to expedite the planning, design, development, and operation of the infrastructure necessary to provide reliable, clean drinking water on Federal Indian reservations, in Alaska Native Villages, and in Native Hawaiian communities; and

(ii) inform Congress of further authorizations and expenditures that may be necessary to meet the objective described in clause (i);

(B) calls upon the Federal executive branch to—

(i) employ a “whole-of-government” approach to ensure the provision of reliable, clean drinking water to households on Federal Indian reservations, in Alaska Native villages, and in Native Hawaiian communities;

(ii) create an interagency task force consisting of high-level representatives from departments and agencies with authority to provide water infrastructure that will work to remove barriers, optimize funding, and make immediate and tangible progress on meeting the objective described in clause (i); and

(iii) report annually to Congress on the progress toward the objective described in clause (i); and

(C) calls upon the Federal executive branch, State governments, and affected water agencies to—

(i) affirmatively support de-coupling the planning, design, development, and operation of water infrastructure from the settlement or adjudication of Tribal reserved water rights; and

(ii) support the development of water infrastructure necessary to provide reliable, clean drinking water in Native communities independent of settlements or adjudications of Tribal reserved water rights.

SENATE RESOLUTION 356—EXPRESSING SUPPORT FOR THE DESIGNATION OF THE WEEK OF SEPTEMBER 18 THROUGH SEPTEMBER 24, 2023, AS “RAIL SAFETY WEEK” IN THE UNITED STATES AND SUPPORTING THE GOALS AND IDEALS OF RAIL SAFETY WEEK TO REDUCE HIGHWAY-RAIL GRADE CROSSING AND TRESPASSER-RELATED INCIDENTS, FATALITIES, AND INJURIES, REDUCE DERAILEMENTS, IMPROVE THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS BY RAIL, AND PREVENT RAIL WORKER FATALITIES

Ms. CANTWELL (for herself, Mr. VANCE, Mr. BROWN, Mr. CASEY, and Mr. FETTERMAN) submitted the following resolution; which was referred to the Committee on Commerce, Science, and Transportation:

S. RES. 356

Whereas the first Rail Safety Week was held from September 24 through September 30, 2017, by the national education safety nonprofit organization Operation Lifesaver, the Department of Transportation, and other organizations;

Whereas Rail Safety Week was launched to raise awareness about the need for increased education on how to be safe around highway-rail grade crossings and railroad tracks and to highlight efforts to further reduce collisions, injuries, and fatalities;